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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/622,124

07/18/2003

Martin F. Bachmann

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7590

02/04/2009

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EXAMINER

BOESEN, AGNIESZKA

ART UNIT

PAPER NUMBER

1648

MAIL DATE

DELIVERY MODE

02/04/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/622,124	Applicant(s) BACHMANN ET AL.	
	Examiner AGNIESZKA BOESEN	Art Unit 1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 October 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 63,68-76,78-88,94,97-116,118-123,126 and 128-139 is/are pending in the application.
- 4a) Of the above claim(s) 74, 99, 105-107, 111-113, 121-123 and 133 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) See Continuation Sheet is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Continuation of Disposition of Claims: Claims rejected are 63,68-73,75,76,78-88,94,97,98,100-104,108-110,114-116,118-120,124,126,128-132 and 134-139.

DETAILED ACTION

The Amendment filed October 16, 2008 in response to the Office Action of April 16, 2008 is acknowledged and has been entered. Applicant's request for rejoinder of process claim 133 is acknowledged.

Claims 95, 117, 124, 125 and 127 have been canceled. Rejections of canceled claims are moot. New claims 134-139 have been added. Claims 63, 68-73, 75, 76, 78-88, 94, 97, 98, 100-104, 108-110, 114-116, 118-120, 124, 126, 128-132 and 134-139 are under examination in this Office action.

Claim Rejections - 35 USC § 103

Rejection of claims 63, 68-73, 75, 76, 78-88, 94, 97, 98, 100-104, 108-110, 114-116, 118-120, 124, 126, 128-132 under 35 U.S.C. 103(a) as being unpatentable over Stockley et al. (US Patent 6,159,728) in view of Deghengi et al. (US 2002/0187938) and further in view of Kojima et al. (Nature, 1999 Vol. 402, p. 656-660) and Maita et al. (Gen Pept Accession VCBPQB, 1971) **is withdrawn** in view of Applicant's amendment.

New rejection in view of Applicant's amendment

The new rejection cites the same references that were cited in the withdrawn rejection and cites one additional reference.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 63, 68-73, 75, 76, 78-88, 94, 97, 98, 100-104, 108-110, 114-116, 118-120, 124, 126, 128-132 and 134-139 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stockley et al. (US Patent 6,159,728) in view of Deghengi et al. (US 2002/0187938), Kojima et al. (Nature, 1999 Vol. 402, p. 656-660) Maita et al. (Gen Pept Accession VCBPQB, 1971) and further in view of Nielsen et al. (US Patent 6,548,651 B1).

Stockley, Daghengi, Kojima and Maita teach the claimed invention as discussed on the record. Stockley teach the covalent attachment of an immunogenic peptide to the cysteine residue of the VLP RNA bacteriophage (see column 10, lines 29-67, column 11, lines 1-35 and column 12, lines 1-30). However Stockley does not teach the non-peptide covalent attachment of an immunogenic peptide to the cysteine residue of the VLP RNA bacteriophage. Stockley does not teach the second attachment site being a lysine residue of the VLP. Sockey does not teach a heterobifunctional cross-linker capable of reacting with first attachment site and a second attachment site, wherein the linker is succinimidyl 6-(β -maleimido-propionamido) hexanoate (SMPH) as required by new claims 134-139.

Nielsen et al. teach a non-peptide heterobifunctional cross-linker succinimidyl 6-(β -maleimido-propionamido) hexanoate (SMPH) covalently linking peptides with nucleic acid molecules representing bacterial antigens through either a cysteine (C) or a lysine (K) residue (see claim 1, Tables 1 and 4, column 8, lines 17-41 and column 9, lines 4-10).

It would have been *prima facie* obvious to the person of ordinary skill in the art to covalently attach Stockley's RNA Q β bacteriophage to Deghengi's and/or Kojima's ghrelin peptide using Nielsen's non-peptide heterobifunctional cross-linker succinimidyl 6-(β -maleimido-propionamido) hexanoate (SMPH) capable of reacting with the first attachment site

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which is a lysine residue and a second attachment site which is a cysteine residue because Nielsen teaches that the SMPH is a suitable linker for attachment of peptides with nucleic acids (see claim 1, Tables 1 and 4, column 8, lines 17-41 and column 9, lines 4-10).

One would have been motivated to use Nielsen's succinimidyl 6-(β -maleimido-propionamido) hexanoate (SMPH) linker to attach Deghenghi's and/or Kojima's ghrelin peptide to Stockley's RNA Q β bacteriophage because Nielsen teaches that the SMPH linker is used to attach peptides and nucleic acid molecules together.

One would have had a reasonable expectation of success to attach Deghenghi's and/or Kojima's ghrelin peptide to Stockley's RNA Q β bacteriophage using Nielsen's SMPH linker because the linker technology has been well established in the art at the time of the present invention as evidenced by Nielsen et al.

Therefore the present claims would have been obvious to those skilled in the art at the time of the present invention.

Response to Applicant's arguments

Applicant's arguments have been fully considered. Applicants argue that neither Stockey, Dehenghi, Kojima or Maita teach non-peptide covalent coupling between the RNA bacteriophage and an antigen of interest or the first attachment site being a lysine residue and the second attachment site being the cysteine residue. The new reference by Nielsen et al. (US Patent 6,548,651 B1) cures the deficiencies of Stockey, Dehenghi, Kojima or Maita as discussed above.

Conclusion

No claim is allowed.

Applicant's amendment necessitated the new ground of rejections presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to AGNIESZKA BOESEN whose telephone number is (571)272-8035. The examiner can normally be reached on Monday – Friday from 9:00 AM to 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Agnieszka Boesen/

Examiner, Art Unit 1648

/Bruce Campell/

Supervisory Patent Examiner, Art Unit 1648